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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,040	08/06/2002	John Edward Andrew Shaw	P 0284114	8906

7590

05/04/2005

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EXAMINER

SIEFKE, SAMUEL P

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/030,040	Applicant(s) ANDREW SHAW ET AL.	
	Examiner Samuel P. Siefke	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8, 10-12, 16, 17, are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (USPN 6,004,822).

Li teaches a device and method for measuring solubility of submilliliter quantities. The apparatus comprises a housing (2) which includes two chamber (17, 19). A solid and a solvent are received in one chamber (col. 6, lines 18-40). A filter is disposed between the two chambers in order to stop (aid and retain) undissolved solids from passing from chamber (17) to chamber (19). The walls and the filter of chamber 17 are surface regions that qualify as surfaces that aid in retaining a solid put in the chamber. A pump is used to force mixing of the solid and solvent. A working volume (predetermined) defined by the chambers 19 and 19 may range from about 10 to 400 ul, however other working volumes may be used depending upon the diameter and stroke distance of the pistons selected by the user (col. 7, lines 29-38). The solution, in chamber 19 is free of undissolved compounds, is then withdrawn and analyzed by appropriate means (detector,) to determine its concentration following suitable dilution with known quantities of additional solvent (col 8, lines 3-12; direct measurement). Li

shows in figure 1 and figure 2 concentration versus time curve for a typical chemical compound in a particular solvent. It is inherent that a rise in the concentration of the dissolved solid in the solvent in chamber 19 correlates to a decrease in the solid sample in chamber 17. This anticipates the limitation claiming a detector that determines if the solid sample is removed from the surface region by the liquid. One can determine the rate of dissolution by reference to the measurement of the solid sample removed from the region and the amount of liquid used over time from this.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-8, 12-14, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Li et al. (USPN 6,004,822) in view of Cowen, S. "Small is Beautiful". Chemistry and Industry. Chemistry and Industry Review, Chemical Society, No. 19, 5 October 1998, pp. 792-793.

Li teaches a device and method for measuring solubility of submilliliter quantities as discussed above.

Li does not teach that the device is microfabricated or the physical structure form of the chamber.

Cowen teaches that there are many reasons for wanting to shrink the laboratory down onto a chip. Smaller instruments mean that the transfer of heat and mass occurs more quickly because shorter distances are involved. This speeds up performance dramatically. Therefore, it would have been obvious to one having an ordinary skill in the art to modify Li to employ a microfabricated device, given the volume, quantity and filter pore size, in order to take advantage of the benefits of such microfabricated devices. Regarding the physical structure of the chamber, it would have been obvious to one having an ordinary skill in the art to modify Li to make the chambers out of a molded structure because a chamber made out of a mold will keep the chamber the same size if one were to provide multiple testing devices. This provides an exact chamber size between devices.

Claims 5-8, 12-14, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Li et al. (USPN 6,004,822) in view of Rippie (US 4,247,298),

Li teaches a device and method for measuring solubility of submilliliter quantities as discussed above.

Rippie teaches a drug dissolution device that comprises a flow through cell that is packed with a cascade barrier bed for measuring the dissolution behavior. The vertical bed is packed in discrete layers with uniform sized, inert particles, progressing from layers of small particles at the bottom to layers of large particles at the top. This solid material to be dissolved, when introduced to the top, is carried down into the bed by gravity and downward flow of the solvent, separated into particle size fractions by the bed, and held in contact with the flowing solvent. It would have been obvious to one having an ordinary skill in the art to modify Li to employ the cascade barrier bed instead of a filter of Li to allow for a solid material to be separated into particle size fractions. This would provide information as to how the solid sample breaks down in solvent over time.

Response to Arguments

Applicant's arguments with respect to claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



May 2, 2005


Jili Varden
Supervisory Patent Examiner
Technology Center 1700